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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,574	04/05/2001	Walter Elger	JENA-6	1528
23599	7590	02/24/2005	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			JIANG, SHAOJIA A	
		ART UNIT	PAPER NUMBER	
			1617	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/744,574	ELGER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Shaojia A. Jiang	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 23 November 2004.  
2a)  This action is FINAL.                  2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

- 4)  Claim(s) 9,11 and 13-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 9,11 and 13-17 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## **Application Papers**

- 9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_ .  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

## DETAILED ACTION

This Office Action is a response to Applicant's response (remarks/Arguments) filed on November 23, 2004 wherein no amendment is filed, i.e., no claims are amended, cancelled, or newly submitted.

Currently, claims 9, 11, and 13-17 are pending in this application.

Claims 9, 11, and 13-17 are currently under examination on the merits.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9, 11, and 13-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 4-7, and 11-18 of U.S. Patent No. 6,653,298, for same reasons of record stated in the Office Action dated October 4, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method for hormone replacement

therapy in a patient in need of thereof comprising administering the compounds having the formula therein encompassing the instant compounds or the same particular compounds recited in claim 12 therein which are the instant specific estrogen sulfamate.

Note that 6,653,298 also discloses the 0.5-2 mg/week (7 days), weekly administration of estrogen sulfamate; and 2-4 mg/month (30 days), monthly administration of estrogen sulfamate, as instantly claimed (see 6,653,298, col.8 lines 8-25). Thus, the patent is deemed to encompass the instant claims.

Therefore, the instant claims 9, 11, and 13-17 are deemed to be obvious over claims 2, 4-7, and 11-18 of U.S. Patent No. 6,653,298.

***Response to Argument***

Applicant's arguments filed November 23, 2004 with respect to this obviousness-type double patenting rejection of record in the previous Office Action have been fully considered but are not deemed persuasive.

Applicant asserts that "the test for obviousness-type double patenting is not whether the patent over which the claims are rejected encompasses the claims. Rather, the test encompasses a two step inquiry".

In this case, when applying two step inquiry or two-way test, the instant claims 9, 11, and 13-17 are deemed to be obvious over the claims 2, 4-7, and 11-18 of U.S. Patent No. 6,653,298, as the claims 2, 4-7, and 11-18 of U.S. Patent No. 6,653,298 would have been obvious over the instant claims 9, 11, and 13-17 as further discussed below.

The patent is drawn to a method for hormone replacement therapy in a patient in need of thereof comprising administering the compounds having the formula therein encompassing the instant compounds or the same particular compounds recited in claim 12 therein which are the instant specific estrogen sulfamate, in a dosage of no greater than 200 µg/day per 70 kg subject. Note that 200 µg/day equals to 0.2 mg/day.

The instant claims are drawn to a method of achieving hormone replacement therapy in a woman comprising administering the specific estrogen sulfamate which is the compound in claim 12 of the patent or encompassed by the claims of the patent at a dosage of 0.5-5.0 mg/day when administered in intervals of 5-10 days.

Note that 0.2 mg/day per 70 kg subject in the patent is deemed close to 0.5-5.0 mg/day, as claimed herein. Moreover, the patent also discloses the 0.5-2 mg/week (7 days), weekly administration of estrogen sulfamate; and 2-4 mg/month (30 days), monthly administration of estrogen sulfamate, as instantly claimed (see 6,653,298, col.8 lines 8-25).

Therefore, the instant claims and the patent claims meet two-way obviousness.

In view of the rejections to the pending claims set forth above, no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

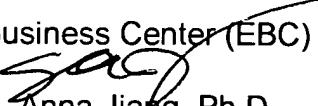
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
S. Anna Jiang, Ph.D.  
Primary Examiner  
Art Unit 1617  
February 8, 2005